IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Marc O. SCHURR et al.	)	Group Art Unit: 3773
	)	
Application No.: 09/957,451	)	Examiner: Darwin P. Erezo
	)	
Filed: September 21, 2001	)	Confirmation No.: 2507
	)	
For: METHODS AND DEVICES FOR FOLDING AND SECURING TISSUE	)	

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Commissioner for Patents
P.O. Box 1450
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Sir:

APPEAL BRIEF UNDER BOARD RULE § 41.37

In support of the Notice of Appeal filed March 3, 2009, and further to Board Rule 41.37, Appellant presents this brief and encloses herewith the fee payment of $540.00 required under 37 C.F.R. § 41.20(b)(2). The period for filing this brief extends to June 29, 2009 (June 27, 2009, being a Saturday), due to the Notice of Panel Decision from Pre-Appeal Brief Review mailed May 27, 2009.

This Appeal responds to the rejection of claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-132, 134, 135, 137, 138, 140, 142-145, 147, 148, 150-155, 157, 164-167, 173-175, and 177-181 in the final Office Action mailed September 9, 2008, in the Advisory Actions Before the Filing of an Appeal Brief mailed December 5, 2008 and February 6, 2009, and in the Notice of Panel Decision from Pre-Appeal Brief Review mailed May 27, 2009.

If any additional fees are required or if the enclosed payment is insufficient, Appellant requests that the required fees be charged to Deposit Account 06-0916.

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Real Party In Interest

Boston Scientific Scimed, Inc. is the real party in interest.

Related Appeals and Interferences

There are currently no other appeals or interferences, of which Appellant, Appellant's legal representative, or Assignee are aware, that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status Of Claims

Claims 3, 4, 6, 8-119, 122, 123, 125, 128, 133, 136, 139, 141, 146, 149, 156, 158-163, 168-172, and 176 have been canceled.

Claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-132, 134, 135, 137, 138, 140, 142-145, 147, 148, 150-155, 157, 164-167, 173-175, and 177-181 are rejected.

Appellant appeals the rejection of claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-132, 134, 135, 137, 138, 140, 142-145, 147, 148, 150-155, 157, 164-167, 173-175, and 177-181. A copy of these claims is provided in the Claims Appendix to Appeal Brief.

Status Of Amendments

In response to the final Office Action mailed September 9, 2008, Appellant filed an Amendment After Final on November 5, 2008, amending claim 4 and canceling claims 172 and 176. In accordance with the Advisory Action mailed December 5, 2008, the Amendment After Final filed November 5, 2008, will not be entered.

Appellant filed a second Amendment After Final on January 9, 2009, canceling claims 4, 172, and 176. In accordance with the Advisory Action mailed February 6, 2009, the Amendment After Final filed January 9, 2009, will be entered for purposes of this appeal. Therefore, the rejection of claim 4 under 35 U.S.C. § 112, second paragraph, is moot. Claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-132, 134, 135, 137, 138, 140, 142-145, 147, 148, 150-155, 157, 164-167, 173-175, and 177-181 remain pending and are involved with this appeal.

Summary Of Claimed Subject Matter

A. Claims 1 and 173

Independent claim 1 is directed to a device for securing a fold of tissue in a medical procedure. (*See, e.g.*, element 300 of Figs. 6A, 7, and 8; and ¶ [73] of Appellant's specification.) The device includes a first arm and a second arm disposed substantially opposite to the first arm. (*See, e.g.*, elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.)

The second arm has a first end fixedly connected to a first end of the first arm to define an opening to receive the fold of tissue. (*See, e.g.*, elements 301, 302, and 307 of Figs. 6A, 7, and 8; ¶¶ [75] and [77] of Appellant's specification.) The first and second arms are configured to extend in substantially the same direction as the fold of tissue and secure to the tissue fold with the arms remaining exterior to an outer surface of the tissue fold. (*See, e.g.*, elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.) The opening is configured to allow tissue to extend from the connection beyond a second end of each of the first and second arms when the tissue is secured, and the second ends of the first and second arms are located opposite the first ends of the first and second arms. (*See, e.g.*, elements 301, 302, and 307 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.)

The second end of the first arm is configured to maintain a non-contacting relationship with the second end of the second arm when the device is in a final tissue-fold-securing position. (*See, e.g.*, elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.) The second end of each of the first and second arms includes a distalmost surface of the respective arm that is furthest from the first end of

the respective arm. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.) The second end of the first arm is configured to maintain a non-contacting relationship with the second end of the second arm when the device is in an initial, normal position. (*See, e.g.,* elements 301 and 302 of Fig. 6A; ¶¶ [73] and [75] of Appellant's specification.)

The first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶¶ [76] and [79] of Appellant's specification.)

At least one of the first and second arms includes an integral anchoring portion protruding from at least one of the first and second arms and configured to maintain a non-contacting relationship with the other of the first and second arms when the device is in the final tissue-fold-securing position. (*See, e.g.,* elements 301, 302, and 304 of Figs. 6A, 7, and 8; ¶ [74] of Appellant's specification.) The other of the first and second arms does not include a structure for receiving the integral anchoring portion. (*See, e.g.,* elements 301, 302, and 304 of Figs. 6A, 7, and 8; ¶ [74] of Appellant's specification.)

Claim 173 depends directly from independent claim 1 and recites that the second end of one of the first and second arms has a crook for providing a surface to push against to bring the arms closer together during insertion. (*See, e.g.,* elements 302 and 306 of Figs. 6A and 8; ¶ [75] of Appellant's specification.)

B. Claims 120, 129, 130, 132, 174, and 175

Independent claim 120 is directed to a clip for treating Gastroesophageal Reflux Disease by being inserted through an esophagus and secured to a fold of tissue to connect fundus wall tissue to esophagus wall tissue. (*See, e.g.,* element 300 of Figs. 6A, 7, and 8; and ¶¶ [11] and [73] of Appellant's specification.) The clip includes a first arm having a distal end and a proximal end, and a second arm having a distal end and a proximal end. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.)

The proximal ends of both the first and second arms are fixedly connected, and the first and second arms are spaced from each other to define a gap therebetween to receive the fold of tissue such that one of the first and second arms is configured to be in contact with the esophagus wall tissue and the other of the first and second arms is configured to be in contact with the fundus wall tissue. (*See, e.g.,* elements 301, 302, and 307 of Figs. 6A, 7, and 8; ¶¶ [75] and [77] of Appellant's specification.)

The first and second arms are sized to be inserted through an esophagus, and the first and second arms are configured to extend in substantially the same direction as the fold of tissue. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶¶[60], [73], and [77] of Appellant's specification.)

The gap is configured to allow tissue to extend from the connection beyond the distal end of each of the first and second arms when the tissue is secured. (*See, e.g.,* elements 301, 302, and 307 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.)

The distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the clip is in a final tissue-fold-

securing position. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.) The distal end of each of the first and second arms includes a distalmost surface of the respective arm that is furthest from the proximal end of the respective arm. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.) The distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the device is in an initial, normal position. (*See, e.g.,* elements 301 and 302 of Fig. 6A; ¶¶ [73] and [75] of Appellant's specification.)

The first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶¶ [76] and [79] of Appellant's specification.)

The clip also includes an integral anchoring portion protruding from at least one of the first and second arms, and configured to maintain a non-contacting relationship with the other of the first and second arms when the clip is in the final tissue-fold-securing position. (*See, e.g.,* elements 301, 302, and 304 of Figs. 6A, 7, and 8; ¶ [74] of Appellant's specification.) The other of the first and second arms does not include a structure for receiving the integral anchoring portion. (*See, e.g.,* elements 301, 302, and 304 of Figs. 6A, 7, and 8; ¶ [74] of Appellant's specification.)

Claim 129 depends directly from independent claim 120 and recites an additional anchoring portion including one of a pin, bolt, suture, staple, and rod configured to pierce the tissue fold. (*See, e.g.,* element 305 of Fig. 6A; ¶ [74] of Appellant's specification.)

Claim 130 depends directly from independent claim 120 and recites that the distal end of one of the first and second arms includes a tapering portion curving away from the gap. (*See, e.g.,* elements 302 and 306 of Figs. 6A and 8; ¶ [75] of Appellant's specification.)

Claim 132 depends directly from claim 131, which depends directly from independent claim 120, and recites a gripping tab configured to engage a medical device used to position the clip. (*See, e.g.,* elements 303 and 310 of Figs. 6A, 6B, and 7; ¶ [74] of Appellant's specification.) Claim 132 recites that the gripping tab is located at the distal end of one of the first and second arms. (*See, e.g.,* elements 301 and 303 of Figs. 6A and 6B; ¶ [74] of Appellant's specification.)

Claim 174 depends directly from independent claim 120 and recites that the anchoring portion includes at least a portion in the shape of a barb configured to penetrate a surface of the fold of tissue. (*See, e.g.,* element 304 of Figs. 6A, 7, and 8; ¶ [74] of Appellant's specification.)

Claim 175 depends directly from independent claim 120 and recites that the distal end of one of the first and second arms has a crook for providing a surface to push against to bring the arms closer together during insertion. (*See, e.g.,* elements 302 and 306 of Figs. 6A and 8; ¶ [75] of Appellant's specification.)

C. <u>Claims 135, 142, 143, 145, and 177</u>

Independent claim 135 is directed to a clip device for securing a fold of tissue in a medical procedure. (*See, e.g.,* element 300 of Figs. 6A, 7, and 8; and ¶ [73] of Appellant's specification.) The device includes a first arm having a proximal end and a

distal end, and a second arm having a proximal end and a distal end. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.)

The second arm is disposed substantially opposite to the first arm, and the proximal end of the second arm is fixedly connected to the proximal end of the first arm to define a gap to receive the fold of tissue. (*See, e.g.,* elements 301, 302, and 307 of Figs. 6A, 7, and 8; ¶¶ [73], [75], and [77] of Appellant's specification.) The first and second arms are configured to extend in substantially the same direction as the fold of tissue and secure to the tissue fold with the arms remaining exterior to an outer surface of the tissue fold. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.) The gap is configured to allow tissue to extend from said connection beyond the distal end of each of the first and second arms when the tissue is secured. (*See, e.g.,* elements 301, 302, and 307 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.)

The distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the clip device is in a final tissue-fold-securing position. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.) The distal end of each of the first and second arms includes a distalmost surface of the respective arm that is furthest from the proximal end of the respective arm. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.) The distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the device is in an initial, normal position. (*See, e.g.,* elements 301 and 302 of Fig. 6A; ¶¶ [73] and [75] of Appellant's specification.)

The first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶¶ [76] and [79] of Appellant's specification.)

The device also includes an anchoring portion integral with one of the first and second arms and configured to engage the fold of tissue in the gap between the first and second arms to assist in securing the clip device to the tissue fold. (*See, e.g.,* elements 301, 302, and 304 of Figs. 6A, 7, and 8; ¶¶ [74] and [77] of Appellant's specification.) The anchoring portion is configured to maintain a non-contacting relationship with the other of the first and second arms when the clip device is in the final tissue-fold-securing position. (*See, e.g.,* elements 301, 302, and 304 of Figs. 6A, 7, and 8; ¶ [74] of Appellant's specification.) The other of the first and second arms does not include a structure for receiving the anchoring portion. (*See, e.g.,* elements 301, 302, and 304 of Figs. 6A, 7, and 8; ¶ [74] of Appellant's specification.)

Claim 142 depends directly from independent claim 135 and recites another anchoring portion including one of a pin, bolt, suture, staple, and rod configured to pierce the tissue fold. (*See, e.g.,* element 305 of Fig. 6A; ¶ [74] of Appellant's specification.)

Claim 143 depends directly from independent claim 135 and recites that the distal end of one of the first and second arms includes a tapering portion curving away from the gap. (*See, e.g.,* elements 302 and 306 of Figs. 6A and 8; ¶ [75] of Appellant's specification.)

Claim 145 depends directly from claim 144, which depends directly from independent claim 135, and recites a gripping tab configured to engage a medical device used to position the clip device. (*See, e.g.,* elements 303 and 310 of Figs. 6A, 6B, and 7; ¶ [74] of Appellant's specification.) Claim 145 recites that the gripping tab is located at the distal end of one of the first and second arms. (*See, e.g.,* elements 301 and 303 of Figs. 6A and 6B; ¶ [74] of Appellant's specification.)

Claim 177 depends directly from independent claim 135 and recites that the distal end of one of the first and second arms has a crook for providing a surface to push against to bring the arms closer together during insertion. (*See, e.g.,* elements 302 and 306 of Figs. 6A and 8; ¶ [75] of Appellant's specification.)

D. Claims 148, 153, 155, 178, and 179

Independent claim 148 is directed to a clip for treating Gastroesophageal Reflux Disease by securing a fold of tissue to connect fundus wall tissue to esophagus wall tissue. (*See, e.g.,* element 300 of Figs. 6A, 7, and 8; and ¶¶ [11] and [73] of Appellant's specification.) The clip includes a first arm having a distal end and a proximal end, and a second arm having a distal end and a proximal end. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.) The proximal ends of the first and second arms are fixedly connected. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.)

The first and second arms are spaced from each other to define a gap therebetween to receive the fold of tissue such that one of the first and second arms is in contact with the esophagus wall tissue and the other of the first and second arms is in

contact with the fundus wall tissue, and the first and second arms are configured to extend in substantially the same direction as the fold of tissue. (*See, e.g.,* elements 301, 302, and 307 of Figs. 6A, 7, and 8; ¶¶ [75] and [77] of Appellant's specification.) The gap is configured to allow tissue to extend from said connection beyond the distal end of each of the first and second arms when the tissue is secured. (*See, e.g.,* elements 301, 302, and 307 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.)

The distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the clip is in a final tissue-fold-securing position. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.) The distal end of each of the first and second arms includes a distalmost surface of the respective arm that is furthest from the proximal end of the respective arm. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶ [73] of Appellant's specification.) The distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the device is in an initial, normal position. (*See, e.g.,* elements 301 and 302 of Fig. 6A; ¶¶ [73] and [75] of Appellant's specification.)

The first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body. (*See, e.g.,* elements 301 and 302 of Figs. 6A, 7, and 8; ¶¶ [76] and [79] of Appellant's specification.)

The clip also includes a projection extending only partially into the gap between the first and second arms when the clip is in the final tissue-fold-securing position.

(*See, e.g.,* elements 301, 302, and 304 of Figs. 6A, 7, and 8; ¶ [74] of Appellant's specification.) The projection is configured to engage at least one of the fundus wall tissue and the esophagus wall tissue to assist in inhibiting movement of the clip relative to the fold of tissue. (*See, e.g.,* elements 301, 302, and 304 of Figs. 6A, 7, and 8; ¶¶ [74] and [77] of Appellant's specification.) The projection is located on one of the first and second arms, and the other of the first and second arms does not include a structure for receiving the projection. (*See, e.g.,* elements 301, 302, and 304 of Figs. 6A, 7, and 8; ¶ [74] of Appellant's specification.)

Claim 153 depends directly from independent claim 148 and recites that the distal end of one of the first and second arms includes a tapering portion curving away from the gap. (*See, e.g.,* elements 302 and 306 of Figs. 6A and 8; ¶ [75] of Appellant's specification.)

Claim 155 depends directly from claim 154, which depends directly from independent claim 148, and recites a gripping tab configured to engage a medical device used to position the clip. (*See, e.g.,* elements 303 and 310 of Figs. 6A, 6B, and 7; ¶ [74] of Appellant's specification.) Claim 155 recites that the gripping tab is located at the distal end of one of the first and second arms. (*See, e.g.,* elements 301 and 303 of Figs. 6A and 6B; ¶ [74] of Appellant's specification.)

Claim 178 depends directly from independent claim 148 and recites that the projection includes at least a portion in the shape of a barb configured to penetrate a surface of the fold of tissue. (*See, e.g.,* element 304 of Figs. 6A, 7, and 8; ¶ [74] of Appellant's specification.)

Claim 179 depends directly from independent claim 148 and recites that the distal end of one of the first and second arms has a crook for providing a surface to push against to bring the arms closer together during insertion. (*See, e.g.,* elements 302 and 306 of Figs. 6A and 8; ¶ [75] of Appellant's specification.)

Grounds of Rejection

A. Claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-131, 134, 135, 137, 138, 140, 142-144, 147, 148, 150-154, 157, 164-167, 174, 178, 180, and 181 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,604,425 to Le Roy ("*Le Roy*") in view of U.S. Patent No. 5,620,452 to Yoon ("*Yoon*").

B. Claims 132, 145, 155, 173, 175, 177, and 179 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Le Roy* in view of *Yoon* and further in view of U.S. Patent No. 3,032,039 to Beaty ("*Beaty*").

Argument

A. The rejection of claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-131, 134, 135, 137, 138, 140, 142-144, 147, 148, 150-154, 157, 164-167, 174, 178, 180, and 181 under 35 U.S.C. § 103(a) as being unpatentable over *Le Roy* in view of *Yoon* should be reversed.

Appellant respectfully requests the Board to reverse the Examiner's rejection of claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 129-131, 134, 135, 137, 138, 140, 142-144, 147, 148, 150-154, 157, 164-167, 174, 178, 180, and 181 under 35 U.S.C. § 103(a) as being unpatentable over *Le Roy* in view of *Yoon*. The rejection is improper because the criteria for establishing a *prima facie* case of obviousness has not been met.

The Examiner has the initial burden of factually supporting any *prima facie* conclusion of obviousness under § 103. *See* M.P.E.P. § 2142. The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. *Id.* Such an analysis should be made explicit and cannot be premised upon mere conclusory statements. *Id.* It has long been held that a proposed modification of the prior art cannot render the prior art "unsatisfactory for its intended purpose" or "change its principle of operation." M.P.E.P. § 2143.01(V)-(VI). Moreover, it is improper to combine references where the references teach away from their combination. M.P.E.P. § 2145(X)(D).

1. Claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 131, 134, 135, 137, 138, 140, 144, 147, 148, 150-152, 154, 157, 164-167, 180, and 181

Claims 1, 2, 5, 7, 120, 121, 124, 126, 127, 131, 134, 135, 137, 138, 140, 144, 147, 148, 150-152, 154, 157, 164-167, 180, and 181 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,604,425 to Le Roy ("*Le Roy*") in

view of U.S. Patent No. 5,620,452 to Yoon ("*Yoon*"). However, the proposed modifications of the clip of *Le Roy* are improper because, as described below, they counter the express teachings of *Le Roy*, frustrate the intended purpose of the clip of *Le Roy*, and change its principle of operation.

a. Modifying the clip of *Le Roy* to be comprised of bioabsorbable material capable of disintegrating in a body is improper

Independent claim 1 recites a device for securing a fold of tissue in a medical procedure including, among other things, "a first arm [and] a second arm . . . wherein the first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body."

Le Roy discloses a clip 10 including leg sections 24 "for use in clamping wound flaps to prevent the flow of blood from severed arteries, capillaries and the like." (*Le Roy*, col. 1, ll. 11-13; col. 2, ll. 47-50; Figs. 1-5.) The clip 10 of *Le Roy* includes projections 18 that are squeezed together using an applicator tool 14 or by hand to allow application and removal of the clip 10. (*Le Roy*, col. 2, ll. 64-69; and Fig. 1.)

In the final Office Action ("Office Action") mailed September 9, 2008, the Examiner acknowledges that *Le Roy* does not disclose that "the first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body," as recited in claim 1. (Office Action, p. 5, ll. 1-2.) However, the Examiner contends that *Yoon* discloses this feature and that "it would have been obvious . . . to manufacture the device of Le Roy with a bioabsorbable

material since it would allow the clip to dissolve in the body without requiring . . . surgery for removal." (Office Action, p. 5, ll. 3-7.)

One of ordinary skill in the art, however, would not modify the clip 10 of *Le Roy* to be comprised of bioabsorbable material, as proposed by the Examiner. *Le Roy* states that the "[c]lip 10 is particularly effective with scalp and back wounds, and . . . abdominal or long flap wounds as may be necessary in extremity work." (*Le Roy*, col. 3, ll. 21-24.) Therefore, *Le Roy* discloses using the clip 10 for external wounds on the patient's skin, not in the patient's body. Accordingly, since the clip 10 of *Le Roy* is for external purposes, there is no motivation to modify the clip 10 of *Le Roy* to be made of bioabsorbable material capable of disintegrating in a body.

In the Advisory Action ("1st Advisory Action") mailed December 5, 2008, the Examiner relies on a portion of *Le Roy* that states that the clip can be located if "lost" within the operative site. (1st Advisory Action, p. 2, ll. 7-8; *Le Roy*, col. 3, ll. 10-12.) The Examiner alleges that, since the clip of *Le Roy* may be lost within the body, the clip may be used internally, and therefore, it would be obvious to form the clip of bioabsorbable material. (1st Advisory Action, p. 2, ll. 7-10.) The Examiner also alleges that "[a] clip used exclusively in external surfaces of the patient will not require [] disclosure" of the clip being "lost" within the operative site. (1st Advisory Action, p. 2, l. 8.)

However, *Le Roy* merely states that the clip may be introduced internally when it is lost by accident. A clip used externally may be lost if the clip enters by accident through an external wound. Therefore, this portion of *Le Roy* does not disclose or suggest using the clip internally. Rather, this portion of *Le Roy* further shows that the clip is not intended to be inside the patient's body and is intended to be located so that it

may be removed from the patient's body. A physician that "loses" a clip in a body while working on an external wound will not simply leave a clip in an unknown place in the body. The physician retrieves it, so as to avoid unintended consequences to the body. *Le Roy* therefore teaches away from using the clip internally and from allowing the clip to remain inside the patient's body. It is improper to combine references where the references teach away from their combination. M.P.E.P. § 2145(X)(D). Therefore, it is improper to modify the clip of *Le Roy* to be comprised of bioabsorbable material capable of disintegrating in a body.

Furthermore, *Le Roy* states that the clip 10 "can be easily and rapidly removed either with applicator 14 or by hand" and that projections 18 on the clip 10 allow the clip 10 to be removed manually. (*Le Roy*, col. 2, ll. 64-67.) The clip 10 of *Le Roy* is specifically designed to be "easily and rapidly removed . . . off the wound flap 16 without noticeable damage to the tissue." (*Le Roy*, col. 2, ll. 68-69.) Therefore, since the clip 10 of *Le Roy* is specifically designed to be easily and rapidly removeable, there is no motivation to modify the clip 10 to allow it to disintegrate in the patient's body, i.e., so that the clip 10 cannot removed by, for example, a tool or hand. For this additional reason, *Le Roy* teaches away from forming the clip of bioabsorbable material capable of disintegrating in a body.

In the Advisory Action ("the 2nd Advisory Action") mailed February 6, 2009, the Examiner does not add to the arguments provided in the 1st Advisory Action, except to say that "hemostatic clips are well known to be used internally for closing internal wounds, as evidenced by [U.S. Patent No.] 4,246,903 to Larkin" ("*Larkin*"). *Larkin* discloses a hemostatic clip that may be applied to "a blood vessel or other internal

tubular member." (*Larkin*, col. 1, ll. 8-10.) However, *Larkin* does not alter the fact that *Le Roy* teaches away from using the clip internally and from forming the clip of bioabsorbable material capable of disintegrating in a body, as noted above.

For at least these reasons, the Examiner has not clearly articulated a reason why independent claim 1 would have been obvious to one of ordinary skill in the art. Independent claims 120, 135, and 148, although of different scope, each includes elements corresponding to those of independent claim 1 discussed above and are patentable for at least the same reasons. U.S. Patent No. 3,032,039 to Beaty ("*Beaty*") was additionally applied against several claims that depend from one of these independent claims. However, *Beaty* does not cure the deficiencies of *Le Roy* and *Yoon* noted above, nor was it cited for such disclosure.

Claims 2, 5, 7, 121, 124, 126, 127, 131, 134, 137, 138, 140, 144, 147, 150-152, 154, 157, 164-167, 180, and 181 are allowable at least due to their dependency on one of independent claims 1, 120, 135, and 148. In addition, each of claims 2, 5, 7, 121, 124, 126, 127, 131, 134, 137, 138, 140, 144, 147, 150-152, 154, 157, 164-167, 180, and 181 recites unique combinations that are neither taught nor suggested by the cited art, and therefore each is also separately patentable.

2. Claims 129 and 142

Claims 129 and 142 depend from independent claims 120 and 135, respectively, and were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Le Roy* in view of *Yoon*. For at least the reasons described above in connection with independent claims 120 and 135, the rejection of claims 129 and 135 is improper because the

proposed modifications of the clip of *Le Roy* counter the express teachings of *Le Roy*, frustrate the intended purpose of the clip of *Le Roy*, and change its principle of operation. In addition, claims 129 and 142 are patentable for at least the following reasons.

a. *Le Roy* and *Yoon* do not disclose or suggest the claimed pin, bolt, suture, staple, or rod

Claim 129 recites "an additional anchoring portion including one of a pin, bolt, suture, staple, and rod configured to pierce the tissue fold." Claim 142 recites similar features.

The Examiner contends that the leg sections 24 of *Le Roy* correspond to the claimed additional anchoring portion, and that the leg sections 24 have "a tip that can be called a pin that is capable of piercing tissues." (Office Action, p. 6, ll. 19-20.) However, *Le Roy* states that the leg sections 24 "terminate in flanges 28 . . . [with] parallel undulations 30," as shown in Figs. 4 and 5, "with blunt or rounded ends 34." (*Le Roy*, col. 2, ll. 50-60.) The sinusoidal undulations 30 of *Le Roy* do not form tips or pins and are not capable of piercing tissue, contrary to the Examiner's assertion. Rather, *Le Roy* states that the configuration "minimiz[es] any pain [to the wound flap] or undue damage to the tissue." (*Le Roy*, col. 2, ll. 60-63.) Accordingly, *Le Roy* does not disclose or suggest "an additional anchoring portion including one of a pin, bolt, suture, staple, and rod configured to pierce the tissue fold," as recited in claim 129 or claim 142.

Yoon does not cure these deficiencies of *Le Roy*, nor was it cited for such disclosure. For at least these reasons, the Examiner has not clearly articulated a

reason why claims 129 and 142 would have been obvious to one of ordinary skill in the art. Accordingly, for at least these additional reasons, claims 129 and 142 are patentable over *Le Roy* and *Yoon*.

3. Claims 130, 143, and 153

Claims 130, 143, and 153 depend from independent claims 120, 135, and 148, respectively, and were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Le Roy* in view of *Yoon*. For at least the reasons described above in connection with independent claims 120, 135, and 148, the rejection of claims 130, 143, and 153 is improper because the proposed modifications of the clip of *Le Roy* counter the express teachings of *Le Roy*, frustrate the intended purpose of the clip of *Le Roy*, and change its principle of operation. In addition, claims 130, 143, and 153 are patentable for at least the following reasons.

a. *Le Roy* and *Yoon* do not disclose or suggest the claimed tapering portion curving *away* from the gap

Claims 130, 143, and 153 recite that "the distal end of one of the first and second arms includes a tapering portion curving away from the gap."

The Examiner appears to contend that *Le Roy* teaches this feature. (Office Action, p. 6, ll. 21-22.) The Examiner contends that the leg sections 24 of *Le Roy* correspond to the claimed arms. (Office Action, Figure on p. 5.) However, the leg sections 24 of *Le Roy* include the flanges 28 that are bent inward into the space between the leg sections 24, as shown in Fig. 3 and 5. The flanges 28 of *Le Roy* are

curved into the slit 12 separating the flanges 28 so that the flanges 28 taper toward the slit 12. (*Le Roy*, col. 2, ll. 56-60 and Fig. 5.) Therefore, even if one were to assume that the leg sections 24 of *Le Roy* correspond to the claimed arms with tapering portions, which Applicant does not concede, *Le Roy* does not disclose that such tapering portions "curv[e] away from the gap," as recited in claims 130, 143, and 153. (Emphasis added.)

Yoon does not cure these deficiencies of *Le Roy*, nor was it cited for such disclosure. For at least these reasons, the Examiner has not clearly articulated a reason why claims 130, 143, and 153 would have been obvious to one of ordinary skill in the art. Accordingly, for at least these additional reasons, claims 130, 143, and 153 are patentable over *Le Roy* and *Yoon*.

4. Claims 174 and 178

Claims 174 and 178 depend from independent claims 120 and 148, respectively, and were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Le Roy* in view of *Yoon*. For at least the reasons described above in connection with independent claims 120 and 148, the rejection of claims 174 and 178 is improper because the proposed modifications of the clip of *Le Roy* counter the express teachings of *Le Roy*, frustrate the intended purpose of the clip of *Le Roy*, and change its principle of operation. In addition, claims 174 and 178 are patentable for at least the following reasons.

a. *Le Roy* and *Yoon* do not disclose or suggest the claimed barb configured to penetrate a surface of the fold of tissue

Claim 174 recites that "the anchoring portion includes at least a portion in the shape of a barb configured to penetrate a surface of the fold of tissue." Dependent claim 178 recites similar features.

The Examiner contends that the flanges 28 of *Le Roy* correspond to the claimed anchoring portion configured to penetrate a surface of the fold of tissue. (Office Action, Figure on p. 5; p. 6, ll. 13-15.) However, as noted above in connection with the rejection of claims 129 and 142, the sinusoidal undulations 30 of *Le Roy* formed at the ends of the flanges 28 are not capable of piercing tissue, contrary to the Examiner's assertion. Accordingly, *Le Roy* does not disclose or suggest that "the anchoring portion includes at least a portion in the shape of a barb configured to penetrate a surface of the fold of tissue," as recited in claim 174 and the similar elements of claim 178.

Yoon does not cure these deficiencies of *Le Roy*, nor was it cited for such disclosure. For at least these reasons, the Examiner has not clearly articulated a reason why claims 174 and 178 would have been obvious to one of ordinary skill in the art. Accordingly, for at least these additional reasons, claims 174 and 178 are patentable over *Le Roy* and *Yoon*.

B. <u>The rejection of claims 132, 145, 155, 173, 175, 177, and 179 under 35 U.S.C. § 103(a) as being unpatentable over *Le Roy* in view of *Yoon* and further in view of *Beaty* should be reversed.</u>

Appellant respectfully requests the Board to reverse the Examiner's rejection of claims 132, 145, 155, 173, 175, 177, and 179 under 35 U.S.C. § 103(a) as being

unpatentable over *Le Roy* in view of *Yoon* and further in view of *Beaty*. The rejection is improper because the criteria for establishing a *prima facie* case of obviousness has not been met.

1. Claims 132, 145, 155, 173, 175, 177, and 179

Claims 132, 145, 155, 173, 175, 177, and 179 depend from one of independent claims 1, 120, 135, and 148, and were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Le Roy, Yoon,* and *Beaty*. However, for at least the reasons described above in connection with independent claims 1, 120, 135, and 148, the rejection of claims 132, 145, 155, 173, 175, 177, and 179 is improper because the proposed modifications of the clip of *Le Roy* counter the express teachings of *Le Roy*, frustrate the intended purpose of the clip of *Le Roy*, and change its principle of operation. In addition, claims 132, 145, 155, 173, 175, 177, and 179 are patentable for at least the following reasons.

a. Modifying *Le Roy* to move the projections of *Le Roy* to the distal ends is improper

The modification of the clip of *Le Roy* proposed by the Examiner is improper because, as described below, it renders the clip unsatisfactory for its intended purpose and changes its principle of operation.

First, the Examiner has improperly characterized the elements of the claims. The Examiner states that "[t]he modified device of Le Roy discloses all the limitations of the claims except for the distal ends of the first and second arm having the tab defining a

crook." (Office Action, p. 7, ll. 6-7.) However, none of claims 132, 145, 155, 173, 175, 177, and 179 recite "a tab defining a crook," as contended by the Examiner. Claims 132, 145, and 155 recite "[a] gripping tab . . . located at the distal end of one of the first and second arms" and do not recite a crook. Claims 173, 175, 177, and 179 recite that the second end or distal end "of one of the first and second arms has a crook for providing a surface to push against to bring the arms closer together during insertion" and do not recite a tab.

Furthermore, it appears that the Examiner contends that the projections 18 of *Le Roy* (best seen in Fig. 3 of *Le Roy*) correspond to the claimed gripping tab or crook. (Office Action, Figure on p. 5.) The Examiner contends that:

> Le Roy discloses tabs located in the proximal [ends of the leg sections 24]. . . . [I]t would have been obvious . . . to modify the device of Le Roy to have the tabs be located on the distal end tabs because such arrangement is well known in the art.

(Office Action, p. 7, ll. 8-13.) Therefore, the Examiner proposes modifying the clip of *Le Roy* to move the projections 18 at the proximal end to the distal end.

Le Roy provides the projections 18 at the <u>proximal</u> end of the device to facilitate insertion of the wound flap in the device, as shown in Figs. 1 and 3. *Le Roy* states that "[w]hen force is applied to the projections [18] they act as levers to spread the longitudinal slit and facilitate the insertion of the wound flap therein." (*Le Roy*, col. 1, ll. 38-40.) *Le Roy* also states that the clip 10 "can be easily and rapidly removed either with applicator 14 or by hand" and that the projections 18 can be squeezed together and act as levers to spread the flanges 28 away from each other, thereby allowing for manual removal of the clip 10. (*Le Roy*, col. 2, ll. 64-67; Fig. 1.) Therefore, the

intended purpose of *Le Roy*, and a primary focus of its invention, is to include the projections 18 at the proximal end and to allow the projections 18 to be squeezed together so that they act as levers that spread the flanges 28 apart.

One of ordinary skill in the art would not modify the clip of *Le Roy* as proposed by the Examiner. It has long been held that a proposed modification of the prior art cannot render the prior art "unsatisfactory for its intended purpose" or "change its principle of operation." M.P.E.P. § 2143.01(V)-(VI). Modifying the clip 10 of *Le Roy* to move the projections 18 to the distal ends of the leg sections 24 would render the clip of *Le Roy* unsatisfactory for its intended purpose and would change its principle of operation. If the projections 18 of *Le Roy* are moved to the distal ends of the leg sections 24, then the projections 18 cannot be squeezed together as levers to spread the flanges of the clip apart. Instead, since the projections 18 would be located at the distal ends of the arms, according to the Examiner's proposed modification, squeezing the projections 18 together would close the clip. Therefore, the modifcation would render the projections 18 of *Le Roy* unsatisfactory for their intended purpose of opening the clip.

Also, the applicator 14 shown in Fig. 1 of *Le Roy* is only capable of squeezing together two parts, e.g., the projections 18 of *Le Roy*. If the clip were modified as proposed by the Examiner, the applicator 14 would merely squeeze the distal ends together. If the projections 18 of *Le Roy* are provided at the distal ends and squeezed together, the flanges of the clip would be forced toward each other to close the clip. Therefore, the applicator 14 of *Le Roy* would be incapable of opening the modified clip. Since the projections 18 and the applicator 14 of *Le Roy* are intended to be used to

open the clip, the proposed modification renders the clip and the applicator 14 unsatisfactory for their intended purposes and changes their principle of operation.

b. Modifying *Le Roy* based on *Beaty* is improper

In addition, the modification of the clip of *Le Roy* based on *Beaty* proposed by the Examiner is improper because, as described below, it renders the clip unsatisfactory for its intended purpose and changes its principle of operation. The Examiner contends that:

> Furthermore, the arrangement taught by Beaty is an equivalent structure for manipulating a clip so one . . . would have found it obvious to substitute a tab on the distal end for the tab on the proximal end since it would yield predictable results (both allow manipulation of the clip).

(Office Action, p. 7, ll. 13-18.)

Beaty discloses an arterial and veinous clamp including a strip of metal 2 that forms a pair of arms 6, 8 with reversely turned tips 14, 16. (*Beaty*, col. 2, ll. 6-9 and 22-23.) However, one of ordinary skill in the art would not have made the substitution proposed by the Examiner because the proposed substitution would render the clip of *Le Roy* unsatisfactory for its intended purpose and would change its principle of operation.

As noted above, the intended purpose of *Le Roy*, and a primary focus of its invention, is to include the projections 18 at the proximal end and to allow the projections 18 to be squeezed together so that they act as levers that spread the flanges 28 apart. However, modifying the clip 10 of *Le Roy* to substitute the reversely turned tips 14, 16 located on the distal ends of the arms of *Beaty* for the proximally-

located projections 18 of *Le Roy* would render the clip of *Le Roy* unsatisfactory for its intended purpose and would change its principle of operation. The tips 14, 16 of *Beaty* at the distal ends cannot be squeezed together as levers to spread the flanges of the clip apart. Instead, since the tips 14, 16 are located at the distal ends of the arms, the tips 14, 16 would close the clip if squeezed together.

Also, the applicator 14 shown in Fig. 1 of *Le Roy* is only capable of squeezing together two parts, e.g., the projections 18 of *Le Roy* or the tips 14, 16 of *Beaty*. If the clip were modified as proposed by the Examiner, the applicator 14 would merely squeeze the tips 14, 16 of *Beaty* together. If the tips 14, 16 of *Beaty* at the distal ends are squeezed together, the flanges of the clip would be forced toward each other to close the clip. Therefore, the applicator 14 of *Le Roy* would be incapable of opening the modified clip using the tips 14, 16 of *Beaty*. Since the projections 18 and the applicator 14 of *Le Roy* are intended to be used to open the clip, the proposed modification renders the clip and the applicator 14 unsatisfactory for their intended purposes and changes their principle of operation.

Accordingly, *Le Roy*, *Yoon*, and *Beaty* do not disclose or suggest the "gripping tab . . . located at the distal end of one of the first and second arms," as recited in claims 132, 145, and 155, or that the second end or distal end "of one of the first and second arms has a crook for providing a surface to push against to bring the arms closer together during insertion," as recited in claims 173, 175, 177, and 179.

For at least these reasons, the Examiner has not clearly articulated a reason why claims 132, 145, 155, 173, 175, 177, and 179 would have been obvious to one of

ordinary skill in the art. Accordingly, for at least these additional reasons, claims 132, 145, 155, 173, 175, 177, and 179 are patentable over *Le Roy, Yoon*, and *Beaty*.

C. Conclusion

For the reasons given above, the pending claims are allowable and reversal of the Examiner's rejections is respectfully requested.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: June 29, 2009

By: _____

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Claims Appendix to Appeal Brief Under Rule 41.37(c)(1)(viii)

1. (Previously presented) A device for securing a fold of tissue in a medical procedure, the device comprising:

a first arm;

a second arm disposed substantially opposite to the first arm and having a first end fixedly connected to a first end of the first arm to define an opening to receive the fold of tissue, wherein the first and second arms are configured to extend in substantially the same direction as the fold of tissue and secure to the tissue fold with the arms remaining exterior to an outer surface of the tissue fold, and said opening being configured to allow tissue to extend from said connection beyond a second end of each of the first and second arms when the tissue is secured, the second ends of the first and second arms being located opposite the first ends of the first and second arms, wherein the second end of the first arm is configured to maintain a non-contacting relationship with the second end of the second arm when the device is in a final tissue-fold-securing position, the second end of each of the first and second arms including a distalmost surface of the respective arm that is furthest from the first end of the respective arm,

wherein the second end of the first arm is configured to maintain a non-contacting relationship with the second end of the second arm when the device is in an initial, normal position;

wherein the first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body; and

at least one of the first and second arms including an integral anchoring portion protruding from at least one of the first and second arms and configured to maintain a non-contacting relationship with the other of the first and second arms when the device is in the final tissue-fold-securing position,

wherein the other of the first and second arms does not include a structure for receiving the integral anchoring portion.

2. (Original) The device of claim 1, wherein the first and second arms are configured to frictionally engage the outer surface of the tissue fold.

3. (Canceled)

4. (Canceled)

5. (Previously presented) The device of claim 1, further including a gripping tab configured to engage a medical device.

6. (Canceled)

7. (Original) The device of claim 1, wherein the first and second arms form a substantially U-shaped configuration.

8. - 119. (Canceled)

120. (Previously presented) A clip for treating Gastroesophageal Reflux Disease by being inserted through an esophagus and secured to a fold of tissue to connect fundus wall tissue to esophagus wall tissue, the clip comprising:

a first arm having a distal end and a proximal end;

a second arm having a distal end and a proximal end, the proximal ends of both the first and second arms being fixedly connected, wherein the first and second arms are spaced from each other to define a gap therebetween to receive the fold of tissue such that one of the first and second arms is configured to be in contact with the esophagus wall tissue and the other of the first and second arms is configured to be in contact with the fundus wall tissue, wherein the first and second arms are sized to be inserted through an esophagus and the first and second arms are configured to extend in substantially the same direction as the fold of tissue, and the gap being configured to allow tissue to extend from said connection beyond the distal end of each of the first and second arms when the tissue is secured, and wherein the distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the clip is in a final tissue-fold-securing position, the distal end of each of the first and second arms including a distalmost surface of the respective arm that is furthest from the proximal end of the respective arm,

wherein the distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the device is in an initial, normal position;

wherein the first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body; and

an integral anchoring portion protruding from at least one of the first and second arms and configured to maintain a non-contacting relationship with the other of the first and second arms when the clip is in the final tissue-fold-securing position,

wherein the other of the first and second arms does not include a structure for receiving the integral anchoring portion.

121. (Previously presented) The clip of claim 120, wherein the anchoring portion is configured to engage the fold of tissue in the gap between the first and second arms to assist in securing the clip to the tissue fold.

122. (Canceled)

123. (Canceled)

124. (Previously presented) The clip of claim 121, wherein the anchoring portion includes at least a portion in the shape of a reverse angle barb.

125. (Canceled)

126. (Previously presented) The clip device of claim 121, wherein the anchoring portion includes two projections, one projection located on each of the first and second arms.

127. (Previously presented) The clip device of claim 126, wherein the two projections are located directly opposite to one another along the first and second arms.

128. (Canceled)

129. (Previously presented) The clip of claim 120, further including an additional anchoring portion including one of a pin, bolt, suture, staple, and rod configured to pierce the tissue fold.

130. (Previously presented) The clip of claim 120, wherein the distal end of one of the first and second arms includes a tapering portion curving away from the gap.

131. (Previously presented) The clip of claim 120, further including a gripping tab configured to engage a medical device used to position the clip.

132. (Previously presented) The clip of claim 131, wherein the gripping tab is located at the distal end of one of the first and second arms.

133. (Canceled)

134. (Previously presented) The clip of claim 120, wherein the first and second arms form a substantially U-shaped configuration.

135. (Previously presented) A clip device for securing a fold of tissue in a medical procedure, the device comprising:

a first arm having a proximal end and a distal end;

a second arm having a proximal end and a distal end, disposed substantially opposite to the first arm and having the proximal end fixedly connected to the proximal end of the first arm to define a gap to receive the fold of tissue, wherein the first and second arms are configured to extend in substantially the same direction as the fold of tissue and secure to the tissue fold with the arms remaining exterior to an outer surface of the tissue fold, and the gap being configured to allow tissue to extend from said connection beyond the distal end of each of the first and second arms when the tissue is secured, and wherein the distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the clip device is in a final tissue-fold-securing position, the distal end of each of the first and second arms including a distalmost surface of the respective arm that is furthest from the proximal end of the respective arm,

wherein the distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the device is in an initial, normal position;

wherein the first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body; and

an anchoring portion integral with one of the first and second arms and configured to engage the fold of tissue in the gap between the first and second arms to assist in securing the clip device to the tissue fold, the anchoring portion configured to maintain a non-contacting relationship with the other of the first and second arms when the clip device is in the final tissue-fold-securing position,

wherein the other of the first and second arms does not include a structure for receiving the anchoring portion.

136. (Canceled)

137. (Previously presented) The clip device of claim 135, wherein the anchoring portion includes a projection.

138. (Previously presented) The clip device of claim 137, wherein the projection includes at least a portion in the shape of a reverse angle barb.

139. (Canceled)

140. (Previously presented) The clip device of claim 135, wherein the anchoring portion includes two projections, one projection located on each of the first and second arms.

141. (Canceled)

142. (Previously presented) The clip device of claim 135, further including another anchoring portion including one of a pin, bolt, suture, staple, and rod configured to pierce the tissue fold.

143. (Previously presented) The clip device of claim 135, wherein the distal end of one of the first and second arms includes a tapering portion curving away from the gap.

144. (Previously presented) The clip device of claim 135, further including a gripping tab configured to engage a medical device used to position the clip device.

145. (Previously presented) The clip device of claim 144, wherein the gripping tab is located at the distal end of one of the first and second arms.

146. (Canceled)

147. (Previously presented) The clip device of claim 135, wherein the first and second arms form a substantially U-shaped configuration.

148. (Previously presented) A clip for treating Gastroesophageal Reflux Disease by securing a fold of tissue to connect fundus wall tissue to esophagus wall tissue, the clip comprising:

a first arm having a distal end and a proximal end;

a second arm having a distal end and a proximal end, the proximal ends of the first and second arms being fixedly connected, wherein the first and second arms are spaced from each other to define a gap therebetween to receive the fold of tissue such that one of the first and second arms is in contact with the esophagus wall tissue and the other of the first and second arms is in contact with the fundus wall tissue and the first and second arms are configured to extend in substantially the same direction as the fold of tissue, and the gap being configured to allow tissue to extend from said connection beyond the distal end of each of the first and second arms when the tissue is secured, and wherein the distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the clip is in a final tissue-fold-securing position, the distal end of each of the first and second arms including a distalmost surface of the respective arm that is furthest from the proximal end of the respective arm,

wherein the distal end of the first arm is configured to maintain a non-contacting relationship with the distal end of the second arm when the device is in an initial, normal position;

wherein the first and second arms are comprised of a bioabsorbable material such that the first and second arms are capable of disintegrating in a body; and

a projection extending only partially into the gap between the first and second arms when the clip is in the final tissue-fold-securing position, the projection being configured to engage at least one of the fundus wall tissue and the esophagus wall tissue to assist in inhibiting movement of the clip relative to the fold of tissue,

wherein the projection is located on one of the first and second arms and

wherein the other of the first and second arms does not include a structure for receiving the projection.

149. (Canceled)

150. (Previously presented) The clip of claim 148, wherein the projection includes at least a portion in the shape of a barb.

151. (Previously presented) The clip of claim 148, wherein the projection is a first projection located on the first arm, and the clip device further includes a second projection located on the second arm.

152. (Previously presented) The clip of claim 151, wherein the first and second projections are located directly opposite to one another along the first and second arms.

153. (Previously presented) The clip of claim 148, wherein the distal end of one of the first and second arms includes a tapering portion curving away from the gap.

154. (Previously presented) The clip of claim 148, further including a gripping tab configured to engage a medical device used to position the clip.

155. (Previously presented) The clip of claim 154, wherein the gripping tab is located at the distal end of one of the first and second arms.

156. (Canceled)

157. (Previously presented) The clip of claim 148, wherein the first and second arms form a substantially U-shaped configuration.

158. - 163. (Canceled)

164. (Previously presented) The device of claim 1, wherein the device does not require removal.

165. (Previously presented) The clip of claim 120, wherein the clip does not require removal.

166. (Previously presented) The clip device of claim 135, wherein the clip does not require removal.

167. (Previously presented) The clip of claim 148, wherein the clip does not require removal.

168. - 172. (Canceled)

173. (Previously presented) The device of claim 1, wherein the second end of one of the first and second arms has a crook for providing a surface to push against to bring the arms closer together during insertion.

174. (Previously presented) The clip of claim 120, wherein the anchoring portion includes at least a portion in the shape of a barb configured to penetrate a surface of the fold of tissue.

175. (Previously presented) The clip of claim 120, wherein the distal end of one of the first and second arms has a crook for providing a surface to push against to bring the arms closer together during insertion.

176. (Canceled)

177. (Previously presented) The clip device of claim 135, wherein the distal end of one of the first and second arms has a crook for providing a surface to push against to bring the arms closer together during insertion.

178. (Previously presented) The clip of claim 148, wherein the projection includes at least a portion in the shape of a barb configured to penetrate a surface of the fold of tissue.

179. (Previously presented) The clip of claim 148, wherein the distal end of one of the first and second arms has a crook for providing a surface to push against to bring the arms closer together during insertion.

180. (Previously presented) The device of claim 1, wherein the integral anchoring portion includes two projections, one projection located on each of the first and second arms, and

wherein the two projections are located directly opposite to one another along the first and second arms.

181. (Previously presented) The clip device of claim 140, wherein the two projections are located directly opposite to one another along the first and second arms.

Evidence Appendix to Appeal Brief Under Rule 41.37(c)(1)(ix)

There is no evidence being relied upon by Appellant in this Appeal.

Related Proceedings Appendix to Appeal Brief Under Rule 41.37(c)(1)(x)

To Appellant's knowledge, there are no related proceedings.